U.S. Agency for International Development (USAID) Updated Guidance on Procuring Personal Protective Equipment (PPE) / Covered Material

Summary:

As a general rule, USAID's implementing partners must seek the prior written approval of the cognizant USAID Agreement or Contracting Officer(s) (AOs/COs) to procure the following commodities (collectively, "Covered Material") with <u>any</u> USAID funds:

- a) N95 Filtering Facepiece Respirators;
- b) Other Filtering Facepiece Respirators;
- c) Elastomeric, air-purifying respirators and appropriate particulate filters/cartridges;
- d) PPE surgical masks;
- e) PPE gloves or surgical gloves;
- f) Ventilators; and
- g) COVID-19 test kits produced in the United States or meant for the United States market.

However, implementing partners may use USAID's funding to procure this Covered Material without further approvals in <u>either</u> of the following two situations:

- 1) For the protection of, and use by, staff under both grants and contracts from USAID:
 - a) In this situation, implementing partners may procure Covered Material from <u>any</u> source; or
- 2) For the safe and effective continuity of USAID-funded programs, including for the protection of beneficiaries (but not for the protection of an implementing partner's staff, which is addressed in #1 above):
 - a) In this situation, implementing partners may procure Covered Material manufactured locally in, or in the same geographical region as, the country in which USAID is providing assistance, as defined by the U.S. Department of State's regional system (<u>Africa</u>, <u>East Asia and the Pacific</u>, <u>Europe and Eurasia</u>, the <u>Near East</u>, <u>South and Central Asia</u>, and the <u>Western Hemisphere</u>), provided that the Covered Materials are not, and could not reasonably be, intended for the U.S. market.

All other PPE and COVID-19 test kits not mentioned above are not restricted from procurement or subject to the requirements described in this guidance. In particular, the procurement of

quality COVID-19 test kits not produced in the United States or intended for the U.S. market for USAID's international programs and projects pursuant to approved Scopes of Work that include the purchase of diagnostics is allowed¹. Cloth masks and other face coverings that do not protect the wearer are not PPE. The procurement of these items is not subject to the limitations set forth in this guidance.

The five categories of PPE included above draw from a temporary <u>rule</u>² issued by the Federal Emergency Management Agency (FEMA) within the U.S. Department of Homeland Security (DHS) and the designation of "scarce or threatened materials" in the "<u>Notice of Designation of Scarce Materials or Threatened Materials Subject to COVID-19 Hoarding Prevention Measures</u>" published in the *Federal Register* by the U.S. Department of Health and Human Services (HHS). This guidance is consistent with DHS/FEMA's temporary <u>rule</u>, which limits exports from the United States of the five types of PPE subject to specific exemptions.

If the Administration issues guidance through a final Presidential Memorandum or other mandate that differs from the approach outlined here, USAID will revise this guidance and require implementing partners to adapt accordingly. USAID has drafted the grant/contract language below to allow the Agency to modify the terms of awards unilaterally in response.

Implementation:

To manage the workflow and prioritize actions in acquisition and assistance, below is the sequence by which USAID will incorporate the new provision below in our awards:

- First, going forward, AOs/COs will include the provision set forth below in <u>all new awards</u> under which implementing partners potentially might procure Covered Material, regardless of the type of funding.
- Second, AOs/COs will work with implementing partners to modify <u>existing awards</u> that include funding from the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (COVID-19 Supplemental) to incorporate the provision.

¹ Right now, nucleic-acid tests are the standard for testing for COVID-19, and point-of-care immunochromatographic rapid diagnostic tests (RDTs) are not recommended for diagnostic use at the moment. Based on current evidence, the World Health Organization recommends the use of rapid diagnostic tests only in research settings (such as eventual performance evaluations compared to other tests), but not clinical decision-making until there is much more evidence to support their use.

² The DHA/FEMA Temporary Rule limited the export of five items from the United States: (1) N95 Filtering Facepiece Respirators; (2) Other Filtering Facepiece Respirators; (3) Elastometric, air-purifying respirators and appropriate particulate filters/cartridges; (4) PPE surgical masks; and, (5) PPE gloves or surgical gloves. It did not preclude the use of U.S. Government funding for the procurement of these items. Additionally, DHS/FEMA subsequently issued exemptions to its export restrictions for the following: (1) Shipments by, or on behalf of, the U.S. Government, including the U.S. military; and, (2) Exports of covered materials by non-profits or non-governmental organizations that are solely for donations to foreign charities or governments for free distribution (not sale) at their destination.

- Third, AOs/COs will work with partners to incorporate the provision in any <u>existing</u> <u>awards</u> under which implementing partners potentially procure Covered Material at the time of <u>any funding modification</u>, including an incremental funding modification, regardless of the type of funding:
 - Implementing partners can continue to purchase Covered Material under existing awards until such time as USAID incorporates the below provision into their awards.

When implementing partners rely on the second exception above regarding the procurement of Covered Material manufactured locally or regionally, they should engage in conversations with vendors and manufacturers to ensure the Covered Material being procured is not, and could not reasonably be, intended for the U.S. market. Implementing partners must document this determination in their files or records, and provide a copy of such documentation to their cognizant AO/CO, who must upload it into the file for the award(s) in USAID's Agency Secure Image and Storage Tracking System (ASIST).

For any other requests to procure Covered Material that does not meet the exceptions described above, COs/AOs must consult with USAID's leadership through the following email inbox: **CoveredMaterials@usaid.gov**

The rules set forth in this guidance will apply as long as the domestic U.S. demand for Covered Material exceeds the available supply. Once a domestic surplus exists for such items in the United States, the Agency might need to revise this guidance.

Grant/Contract Language Consistent with the Above Guidance:

Procurement of "Covered Material"

- 1. Except as provided in paragraph 2 below, and notwithstanding anything in this [award or contract] to the contrary, no funds under this [award or contract] may be used for the procurement of "Covered Material" as listed below without the prior written consent of the [Contracting/Agreement] Officer. For purposes of this [provision or special contract requirement], "Covered Material" shall consist of the following:
 - N95 Filtering Facepiece Respirators, including devices that are disposable, half-face-piece, non-powered, air-purifying particulate respirators intended for use to cover the nose and mouth of the wearer to help reduce the wearer's exposure to pathogenic, biological, airborne particulates;
 - Other Filtering Facepiece Respirators (e.g., those designated as N99, N100, R95, R99, R100, P95, P99, or P100), including single-use, disposable, half-mask respiratory protective devices that cover the user's airway (nose and mouth) and offer protection from particulate materials at an filtration- efficiency level

equivalent to an N95 filtering facepiece respirator according to Section 84.181 of Title 42 of the Code of Federal Regulations (CFR);

- Elastomeric, air-purifying respirators and appropriate particulate filters/cartridges;
- PPE surgical masks, including masks that cover the user's nose and mouth and provide a physical barrier to fluids and particulate materials;
- PPE gloves or surgical gloves, including those defined at Sections 880.6250 (exam gloves) and 878.4460 (surgical gloves) of Title 21 of the CFR and such gloves intended for the same purposes;
- Ventilators; and
- COVID-19 test kits that are meant for the United States market.

For clarity, non-medical grade masks, including cloth masks, are not included in the list of Covered Material above. Further, USAID may modify the list of Covered Material from time-to-time, in writing; any such changes to the list shall apply prospectively.

- 2. The restrictions set forth in paragraph 1 above shall not apply to the procurement of Covered Material:
 - (a) for the protection of and use by the [recipient's or contractor's] or sub-[recipient's or contractor's] staff; or
 - (b) for the safe and effective continuity of USAID-funded programs, including for the protection of beneficiaries, provided that such items are manufactured locally or in the same geographical region as the country in which USAID is providing assistance, as defined by the U.S. Department of State's regional system (<u>Africa</u>, <u>East Asia and the Pacific</u>, <u>Europe and Eurasia</u>, <u>Near East</u>, <u>South and Central Asia</u>, and <u>Western Hemisphere</u>), and provided that such items are not, and could not reasonably be expected to be, meant for the United States market.

The [AO or CO] may change the exemptions set forth in this paragraph in writing; any such changes shall apply prospectively.

- 3. "Staff" for the purposes of the Exception in 2(a) is defined as any individuals receiving financial compensation from the recipient or contractor or sub-recipient or subcontractor.
- 4. For each purchase of Covered Material under Exception 2(b), the recipient or contractor must provide the AO/CO with contemporaneously dated documentation that the order of Covered Material is not meant for, and could not reasonably be meant for, the U.S. market. The AO/CO will then upload the statement into ASIST. This documentation can take the form of a simple email verification from a vendor or a brief, contemporaneously dated, written statement or e-mail from the recipient or contractor confirming its conversation with the vendor.